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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,817	09/17/2003	Harry A. Dugger III	3633-038-999	4051

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EXAMINER
HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,817	DUGGER, HARRY A.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 11/22/05. No claims are cancelled while new claims 23-29 are added. Accordingly claims 14-29 are pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deihl (WO 9413280) in view of Fassberg et al (EP 0656206A1) and further in view of Kanios et al (5,719,197).

Deihl teaches a sprayable analgesic composition comprising an analgesic compound which is absorbed into the bloodstream through the buccal mucosa and a pharmacologically acceptable liquid carrier. In a preferred embodiment the active agent is ibuprofen and the liquid carrier is aqueous ethanol (see page 3). The formulation may also contain other ingredients such as surfactants, humectants, flavoring agents, etc (see page 4). The table in example I shows the concentration ranges of each ingredient. Deihl fails to disclose other suitable active agents for the said formulation, or the use of other solvents including polyethylene glycol and non-polar solvent.

Fassberg discloses aerosol, formulations for oral or nasal administration, which comprise a medicament, an excipient, propellant and optionally surfactants. The suitable excipients include alcohols, polyethylene glycols, short chain fatty acids, etc (see page 3). Fassberg discloses that any pharmaceutically active agent which can be delivered by oral or nasal inhalation may be

used. Examples include antihistamines, antiallergics, analgesics, antibiotics, steroids, bronchodilators, antihistamines, etc (see page 5, lines 42-50).

Kanios et al, discussed in detail in previous Office Actions, teaches formulations that can be in a spray format. The said formulations may contain any one or more of the active agents listed in columns 12-31, including cyclosporine, clozapine, zidevudine, erythromycin, ondansetron, phenytoin, cimetidine, etc.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of formulations for buccal mucosal administration, to have looked in the art for other specific solvents suitable for spray formulations of liquid carriers, as taught by Fassberg et al, with reasonable expectations of successfully preparing suitable formulations for various therapies. Furthermore it is obvious to one of ordinary skill in the art to have substituted any suitable active agent for the analgesics of Diehl's buccal spray formulations as claimed as taught by Kanios et al.

Double Patenting

Claims 1-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-34, 54-59, 80-82 of copending Application No. 09/537,118 in view of Kanios et al (5,719,197). The double patenting rejection is proper because the examined claims and the reference claims are substantially the same. The difference between claims of the instant application and the claims of the co-pending application '118 is the active agents. Kanios teaches that various active agents can be used in base

formulations. Thus it would have been obvious to have substituted active agents in the same base formulations.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 11/22/05 have been fully considered but they are not persuasive.

Applicant argues that Deihl does not disclose a non-polar solvent or the concentration range of 30-99% for a solvent as stated in instant claims. That Fassberg teaches formulations comprising propellants and that Kanios's final product is not administered directly to the oral mucosa.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). As stated in the Office action, Fassberg and Kanios remedy the deficiencies of Deihl. Fassberg discloses non-polar solvent and certain active agents. Kanios also teaches formulations comprising solvents and various active agents. One of ordinary skill in the art would be more than capable of combining the references to improve on the efficiency of a formulation. Furthermore it would have been obvious to one of ordinary skill in the art to have optimized concentration ranges of ingredients. Optimization of ranges are not support for patentability.

It is also noted that in claims 1-20, composition claims, intended use limitations are not given any weight. Thus, to meet the limitations of such claims, Kanios is not required to teach administration to the oral mucosa. Kanios does teach all the ingredients of the said claims.

Applicant states that "examiner does not identify which claims of the US patent or the co-pending application would have rendered obvious claims 1-22 of the current application". However since the claims of the co-pending application were similar to the instant claims, it did not seem necessary to identify them. The difference between claims of the instant application and the claims of the co-pending application '118 is the active agents. Kanios teaches that various active agents can be used in base formulations. Thus it would have been obvious to have substituted active agents in the same base formulations.

Applicant also argues that neither application has been indicated as allowable, thus the objection should "be held in abeyance until such time when allowable subject matter is identified in this application". It is noted that co-pending application 09/537,118 has been allowed, although not yet issued.

NOTE: Certain concentration ranges in the claims, such as "37 and 98.58" in claims 14 and 23, "60 and 90.06" in claims 16 and 25 and "0.005-55" in claim 14, etc, do not correspond to concentration ranges stated in the specification (e.g. pages 2-4). Before allowance such concentration ranges should be corrected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mina Haghighatian
March 3, 2006

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER